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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/780,435 | 02/17/2004 | Robert D. Kross | K15-007.CIP/K15-017 | 1559 |
| 28156 | 7590 | 08/30/2006 | EXAMINER | |
| COLEMAN SUDOL SAPONE, P.C. 714 COLORADO AVENUE BRIDGE PORT, CT 06605-1601 | | | ISSAC, ROY P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1623 | |

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/780,435

Applicant(s)

KROSS ET AL.

Examiner

Roy P. Issac

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/3/06;5/3/04;2/17</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Application

This application is a CIP of 10/041,310 filed 01/07/2002 (abandoned) and claims benefit of 60/511,916 filed 10/17/2003. Currently, claims 1-20 are pending and are examined on the merits herein.

Information Disclosure Statement

The information disclosure statements submitted on 03 May 2004 and 17 February 2004 contain the same references. The references are considered.

Claim Objections

Claims 12 and 13 are objected to because of the following informalities: Claims 12 and 13 recites "a method of claim 1." However, claim 1 is directed to a composition. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, the only independent

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claim in the application recites the phrase "relatively constant" in reference to pH. The phrase "relatively constant" is not clearly defined in the specification and it is not clear which pH levels are excluded and what degree of variation is allowed by the term "relatively constant." Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to the composition encompassed by the recited phrase "relatively constant."

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 recite the term "surface active material." The term is not clearly defined in the specification and renders the claim indefinite.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5, recites the term "comparable" which is not clearly defined in the specification. The recitation of the term "comparable" renders the claim indefinite.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's recitation, "five minutes or more," without an upper limit renders the claim indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

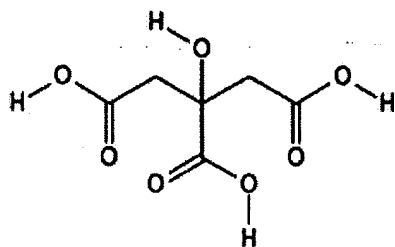
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 14, 16 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Xu et. al. (The bactericidal effect and chemical reactions of acidified nitrite under conditions simulating the stomach; Journal of applied microbiology, April 2001, 90, 523-529; PTO-892, Cited by the examiner).

Xu et. al. discloses the use of nitrite in citric acid-phosphoric acid buffer (pH 3.3 and 2.5) as an antimicrobial agent. (Abstract and Page 524, Column 2, Paragraph 3). Xu et. al teaches that citric acid and nitrite are present in gastric juices and nitrite is present in saliva. (Page 524, Column 1, paragraph 1). Note that applicant defines “nitrite” or “nitrite salt” as a salt of nitrous acid. (Page 5, Second paragraph under “Detailed description of the invention). The specification shows the ratio of nitrous acid to nitrite under various pH conditions. (Table 1, Page 8). Specification shows that at pH 3.3, the ratio of nitrous acid to nitric acid is 1:1 (50% HNO₂ and 50% NO₂⁻). (Table 1, Page 8). The ratio is 83.3 to 16.7 Nitrous acid:Nitrite at pH 2.3. (Table 1, Page 8). The protonation of dissolved nitrite ions under low pH conditions produces nitrous acid. Xu et. al.

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teaches that nitrite in pH 3.3 phosphate-citrate buffer has bactericidal effect against E-Coli. (Page 525, Column 2, Paragraph 1 and Table 1). Xu et. al. reports a reduction in E-Coli count on the log scale of 7.18 to less than 1 in 3 hours. (Table 1, 10mg Nitrite, Citrate-phosphate buffer). Xu et. al. further reports significant decreases in microbial count after treatment with nitrite solution in citrate-phosphate buffer at pH 2.5. (Page 526, Table 3). Even though Xu et. al. does not report the long term pH variability of the nitrite solution, it is expected to remain stable because citrate-phosphate is a strong buffer in acidic conditions. As such, the recitation "the pH of the composition either remains relatively constant at an initial value of around 3.75 or lower, or decreases from said initial value of around 3.75 or lower at the time of formulation to a value as low as around 2.5 over a period of at least about two days, preferably about two days to five days;" is considered a description of an inherent property of the nitrite solution in citrate-phosphorous buffer at pH 3.3. Note that citric acid (structure shown below) is has the alpha hydroxyl acid structure of claim 3.



Xu et. al. describes the use of agar which is considered as a thickener. (Page 524, Column 1, last paragraph). The buffer solution of Xu et. al. is considered an "application medium" recited in claim 7.

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The recitations "wherein the composition may be sprayed onto a substrate, " "teat dip" and "wherein the composition is an oral rinse" are considered as intended uses of the composition. Note that it is well settled that "intended use" of a composition or product, will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

The recitations, "the composition exhibits cidal activity against microorganisms for a period of two months after formulation," "wherein the cidal activity of the composition over a period of about twenty four months or more after formulation is comparable to the activity that it demonstrated initially," and wherein the cidal activity of the composition over a period of about five minutes or more after formulation is equivalent to the activity necessary to achieve an approximately eight log decrease in a sample of E.Coli" are considered functional recitations or inherent properties. The prior art compositions discussed above are expected to show such functional properties because they are deemed to be the same compositions comprising same ingredients.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Benjamin et. al.(PTO-1449, Included by the applicant).

Benjamin et. al. discloses acidified nitrite as an antimicrobial agent. (Page 1, lines 3-4). Benjamin et. al. further discloses that the acidification of nitrite

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produces nitrous acid. (Equation 1, Page 1, line 36). Benjamin et. al. discloses the use of nitrites below pH 4 and the use of metal nitrate as precursor for nitrite ions. (Page 3, lines 20-25). Benjamin et. al. discloses the use of acidified nitrites in carriers such as cream or ointment. (Page 3, lines 27-30). Note that ointment and cream are considered as gel. The acidified nitrite is disclosed for use in either liquid or tablet form. (Page 3, lines 35-36). Benjamin et. al. further discloses a method for sterilizing using acidified nitrite. (page 4, lines 1-10). Benjamin et. al. further discloses the use of citrate/phosphate buffer in which sodium nitrite was added to produce an acidified nitrite solution. (Page 5, Example 1). Benjamin et. al. further discloses the use of acidified nitrite solution against E.Coli. (Page 6, Example 2, lines 20-23). Benjamin et. al. discloses that 1mM concentration of nitrite solution can kill E.Coli completely. (Page 7, Example 3, lines 7-8). Benjamin et. al. further discloses the use of salicylic acid and sodium nitrite on patient feet with fungal infection. (Page 7, Example 5, lines 33-37). Note, that feet is considered mammalian tissue. Benjamin et. al. further discloses the use of acidified nitrites as mouthwash. (Page 8, Example 6, lines 8-14). Benjamin et. al. further discloses the sue of nitrite solution for sterilizing objects such as dentures. (page 2, lines 32-35). Note that, objects such as dentures are considered to have some partial metal surfaces. Since Benjamin et. al. discloses the use of citrate-phosphate buffer, a well known buffer in acidic conditions, it is expected to keep the pH relatively constant and thus keep the cidal activity of the acidic nitrite solution for two months or longer even twenty-four months.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-13, 15 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et. al. (PTO-892, Cited by the examiner), in view of Kross et. al. (U.S. Patent No. 6,603,425; PTO-1449, Included by the applicant).

The disclosure of Xu et. al. is described above in the §102 rejection.

Xu et. al. does not expressly disclose the use of metal nitrite to generate nitrous acid or the composition in the form of a teat dip or gel or a gel with a thickener or the methods of disinfecting a substrate or method of disinfection of a substrate over a period of several months.

Kross et. al discloses the use of antimicrobial agents to disinfect meat carcass. (Abstract). Kross et. al. notes that "Thus, there is a continuing need for an effective and safe spray disinfectant to apply to animal carcasses soon after the evisceration process, before contaminating organisms can develop a firm foothold on the meat surfaces." Kross et. al. discloses the use of low pH antimicrobial agents containing citric acid. (Column 2, example 1). Kross et. al. further discloses the use of phosphoric acid with pKa of 2.15. (column 3, lines 40-45).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to use disinfectant containing nitrite to clean surfaces because Xu et. al. discloses the usefulness of nitrites in low pH solutions as antibacterial agents and Kross et. al. discloses the use of antibacterial agents to disinfect meat surfaces.

One having ordinary skill in the art would have been motivated to do this because Kross et. al. discloses the need for effective and safe disinfectant and Xu et. al. teaches that nitrites are naturally present in gastric juices and saliva and are effective antibacterial agents.

Thus, no claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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